The Changing Face of Quality
Related to the Nuclear Renaissance

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Introduction

> Changing market
  - Nuclear renaissance
  - Global marketplace
  - Higher levels of expectations and scrutiny

> Focused areas of significant change
  - Nuclear Regulatory Commission (NRC) expectations and concerns
  - Institute of Nuclear Power Operations (INPO) Assists
  - American Society of Mechanical Engineers (ASME) expectations
  - Customer expectations
  - Supply Chain challenges
  - Resource Issues
NRC Expectations

> NRC Changes and Expectations

- Re-organized to introduce the NRO (New Reactors) group to focus on new builds
- SECY-07-0105, Vendor Inspection Program
  - Focused on new reactor licensing and construction
  - Increased inspection frequency
  - Increased scrutiny
  - Global marketplace
  - Influence on Codes and Standards
- NRC trend in recent inspection findings and overall concerns
  - Corrective Action Program
  - 10 CFR 21
  - Commercial Grade Dedication
  - Fraudulent supply items
Purpose

- To inform the Commission that the Office of New Reactors (NRO) is enhancing the NRO Vendor Inspection Program (VIP) in support of new reactor licensing and construction
- To describe these enhancements, including the development of program guidance and an anticipated increase in audit and inspection activities

Significant factors that led to expand oversight of nuclear component suppliers include the following:

- The entry of new suppliers to the U.S. nuclear industry
- The use of modular construction techniques
- Inspections, tests, analyses, and acceptance criteria (ITAAC) verification
- Engineering and licensing support services to most applicants
NRO Vendor Inspection Program

> To the extent practical, leverage international regulatory oversight
  - Currently being developed under Multi-National Design Evaluation Program (MDEP)
  - ISO 9001 v. 10 CFR 50, App. B

> NRC participation in Codes & Standards Development
  - ASME Section III & QAI
  - ASME NQA-1
**NRC Expectations**

> NRC trend in recent inspection findings and overall concerns

- **Corrective Action Program**
  - Overdue evaluations and actions
  - Self-Identification of issues

- **10 CFR 21**
  - Errors in a vendor’s evaluation, conclusion, and recommended reporting
  - Vendor not meeting the timeliness requirements
  - No procedural guidance existed for determining if a significant condition adverse to quality as part of the corrective action program within the Appendix B to 10 CFR Part 50 (Appendix B) QA program warranted a 10 CFR Part 21 evaluation
  - Vendor evaluations performed under the corrective action program were utilized as the 10 CFR Part 21 evaluations
NRC Expectations

- **NRC trend in recent inspection findings and overall concerns**
  - **Commercial Grade Dedication**
    - Commercial-grade surveys are **not** a generic programmatic review of a supplier’s quality program.
    - Commercial-grade surveys should focus on verifying the specific critical characteristics for the item being supplied/purchased.
  - A safety function determination should:
    - Consider both design bases and parts classification (e.g., seismic and environmental qualification).
  - An engineering evaluation should:
    - Identify design/performance attributes (critical characteristics) necessary to perform safety-related structures, systems, and components (SSC) safety function.
  - Procurement activities should:
    - Confirm the engineering evaluation (e.g., surveys, testing).
NRC Expectations

NRC trend in recent inspection findings and overall concerns

- Fraudulent Supply Items
  - Suppliers must be monitored to ensure that fraudulent items do not enter the supply chain
  - Receipt inspection
  - Annual Supplier Evaluation
  - Supplier Audits

- Examples
  - Valve Replacement Parts
  - Refurbished Valves
  - Refurbished circuit breakers
INPO Assists

INPO Assists performed in 2008 focused partially in the following areas:

- Corrective Action Program
- Self-Assessment Program
- Lessons Learned
- Operating Experience
- Expectation is for excellence
  - Scoring and comparing utilities is driving performance improvements
ASME Changes and Expectations

- Increased NRC scrutiny
- Improve quality of ASME surveys
  - Increased survey frequency
  - Survey team size increases
  - Survey length increases
  - More thorough surveys
  - Surveys in remote locations
- Quality Deficiencies
  - Open after the survey
  - Possible delay in renewal of certifications
- New survey checklists being developed
- Surveys will focus on actual implementation as opposed to demonstrations
- Increased focus on Nuclear Industry Assessment Committee (NIAC)
Customer Expectations

> Customer Changes and Expectations

- Increased customer scrutiny
  - Mega - NUPIC audits include large teams for longer periods of time at different locations
- Increased interest in continuous improvement efforts – focused on excellence as opposed to precise compliance
  - Corrective Action Program
  - Self-Assessment Program
  - Lessons Learned
  - Operating Experience
  - Metrics/Key Performance Indicators
  - Safety (nuclear and industrial)
  - More critical self-questioning organization
  - AREVA as one company
Supply Chain

> Supply Chain challenges

- Increase in new suppliers to the nuclear industry
- Increase in suppliers who withdrew from the industry and are now trying to return
- Strong nuclear quality culture with a clear understanding of the applicable NRC regulations
  - 10 CFR 50, App. B
  - 10 CFR 21
- Increase in NIAC membership
- Increased scrutiny by regulatory bodies and utilities
- Suppliers involved with Commercial Grade Dedication activities need rigorous engineering involvement
- May require extensive quality and procurement efforts from utilities and contractors to ensure supplier compliance and understanding
Resource Needs

- **Resource Needs**
  - Lack of resources and aging workforce throughout our industry
  - Specifically in Quality, qualifications require special training and time to internalize
    - Lead Auditors
    - QC Inspectors
    - Root Cause Investigators
  - Lessons Learned training for the industry
  - Training challenges
    - “Route and read” training is ineffective
  - Increased training and qualification of personnel performing work
    - New employees entering the nuclear industry
    - Technical training
Summary

> Industry can expect increased oversight from NRC, ASME, and other regulatory bodies
> Contractors/Suppliers will be closely monitored by customers
> Enhanced emphasis on 10 CFR 21 and how it is applied
> Enhanced emphasis on Commercial Grade Dedication
> New suppliers in the industry will need to be coached and monitored closely to gain good understanding of nuclear industry requirements
> Need to provide training on lessons learned in the industry
> Increased training and qualification of personnel performing work
> Industry is focused on excellence as opposed to just compliance
Questions?